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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Agency for Healthcare Research and Quality Agency Information Collection Activities:

Proposed Collection; Comment Request

AGENCY: Agency for Healthcare Research and Quality, HHS.

ACTION: Notice.

SUMMARY: This notice announces the intention of the Agency for Healthcare Research and Quality (AHRQ) to request that the Office of Management and Budget (OMB) approve the proposed information collection project: "Development of a Health Information Rating System (HIRS)." In accordance with the Paperwork Reduction Act, 44 U.S.C. 3501-3521, AHRQ invites the public to comment on this proposed information collection.

DATES: Comments on this notice must be received by [insert date 60 days after date of publication]

ADDRESSES: Written comments should be submitted to: Doris Lefkowitz, Reports Clearance Officer, AHRQ, by email at [doris.lefkowitz@AHRQ.hhs.gov](mailto:doris.lefkowitz@AHRQ.hhs.gov).

Copies of the proposed collection plans, data collection instruments, and specific details on the estimated burden can be obtained from the AHRQ Reports Clearance Officer.

FOR FURTHER INFORMATION CONTACT: Doris Lefkowitz, AHRQ Reports Clearance Officer, (301) 427-1477, or by email at [doris.lefkowitz@AHRQ.hhs.gov](mailto:doris.lefkowitz@AHRQ.hhs.gov).

SUPPLEMENTARY INFORMATION:

Proposed Project

Development of a Health Information Rating System (HIRS)

Over the past several years, low health literacy has been identified as an important health care quality issue. Healthy People 2010 defined health literacy as 'the degree to which individuals have the capacity to obtain, process, and understand basic health information and services needed to make appropriate

health decisions'. In 2003, the Institute of Medicine identified health literacy as a cross-cutting area for health care quality improvement. According to the 2003 National Assessment of Adult Literacy, only 12 percent of adults have proficient health literacy.

Persons with limited health literacy face numerous health care challenges. They often have a poor understanding of basic medical vocabulary and health care concepts. A study of patients in a large public hospital showed that 26 percent did not understand when their next appointment was scheduled and 42 percent did not understand instructions to "take medication on an empty stomach". In addition, limited health literacy leads to more medication errors, more and longer hospital stays, and a generally higher level of illness, resulting in an estimated excess cost for the US health care system of \$50 billion to \$73 billion per year.

Health care providers can improve their patients' health outcomes by delivering the right information at the right time in the right way to help patients prevent or manage chronic conditions such as diabetes, cardiovascular disease, hypertension, and asthma. Electronic health records (EHRs) can help providers offer patients the right information at the right time during office visits, by directly connecting patients to helpful resources on treatment and self-management. EHRs can also facilitate clinicians' use of patient health education materials in the clinical encounter. However, health education materials delivered by EHRs, when available, are rarely written in a way that is understandable and actionable for patients with basic or below basic health literacy – an estimated 77 million people in the United States.

In order to fulfill the promise of EHRs for all patients, especially for persons with limited health literacy, clinicians should have a method to determine how easy a health education material is for patients to understand and act on, have access to a library of easy-to-understand and actionable materials, understand the relevant capabilities and features of EHRs to provide effective patient education, and be made aware of these resources and information. Therefore, AHRQ developed a project that includes the following four major tasks: 1) develop a valid and reliable Health Information Rating System (HIRS), 2) create a library of patient health education materials, 3) review EHR's patient education capabilities and features, and 4) educate EHR vendors and users. This project relates to the first task only.

As a first step, AHRQ has developed a draft HIRS using the following rigorous multistage approach that draws upon existing rating systems, the evidence base in the literature, and the real-world expertise and experience of a Technical Expert Panel (TEP):

- 1) Gather and synthesize evidence on existing rating systems and literature on consumers' understanding of health information. Seek TEP review of the summary of existing health information rating systems. Develop item pool for each domain - understandability and actionability, defined as follows:

- Health education materials are understandable when consumers of diverse backgrounds and varying degrees of health literacy can process and explain key messages.

- Health education materials are actionable when consumers of diverse backgrounds and varying levels of health literacy can identify what they can do based on the information presented.

2) Assess the face and content validity of the domains (i.e., understandability and actionability) with the TEP.

3) Assess the inter-rater reliability of the HIRS on English-language health education materials. Seek TEP review of results and provide guidance on how to address discrepancies.

The draft HIRS was used by AHRQ researchers to rate 2 sets of patient health education materials: a set of 6 education materials related to asthma and a set of 6 education materials related to colonoscopy. Each of these 12 health education materials received a score for their understandability and actionability. Some of the materials received good scores on the draft HIRS, meaning that the researchers considered them to be understandable or actionable, and some materials received poor scores on the draft HIRS, indicating that the materials had low understandability or low actionability.

The final stage of developing a reliable and valid rating system to assess the understandability and actionability of health education materials is testing with consumers.

This project has the following goals:

1) To assess the construct validity of AHRQ's draft HIRS. The 12 rated health education materials will be tested with a total of 48 English-speaking consumers. Consumers will review materials and be asked questions to test whether they understand the materials and whether they know what actions to take. The outcome of this testing will be an HIRS that will offer professionals (e.g., clinicians, health librarians, etc.) a systematic method to evaluate and compare the understandability and actionability of health education materials. Since actionability is a new domain, we are testing it distinct from understandability though there is a theoretical relationship between the domains as we have defined them; that is, a material cannot be actionable if it is not first understandable. So actionability may in fact be a sub-domain of understandability. Besides assessing the construct validity, consumer testing will help us determine how to revise and improve the HIRS.

2) Finalize the HIRS and instructions for users, and make them publicly available on AHRQ's website.

This study is being conducted by AHRQ through its contractor, Abt Associates, pursuant to AHRQ's statutory authority to conduct and support research on health care and on systems for the delivery of such care, including activities with respect to the quality, effectiveness, efficiency, appropriateness and value of health care services and with respect to quality measurement and improvement. 42 U.S.C. 299a(a)(1) and (2).

## Method of Collection

To achieve the goals of the project the following data collections and activities will be implemented:

1) Demographic Questionnaire – The demographic questionnaire will collect basic demographic information about each participant. This data will allow the analysis to detect differences in health literacy by population subgroups.

2) Short Test of Functional Health Literacy in Adults (S-TOFHLA) Questionnaire – The S-TOFHLA will be administered once to all participants to assess their level of health literacy.

3) Health Education Materials & Questionnaire – Asthma/Inhaler – This includes a set of educational materials related to asthma and proper use of inhalers. Each consumer will be randomly assigned one of the six following materials:

i) an audiovisual material (understandable and actionable), titled How to use an inhaler by the Utah Department Health Asthma Program

ii) an audiovisual material (understandable and poorly actionable), titled Asthma Triggers by Children's Healthcare of Atlanta

iii) an audiovisual material (poorly understandable), titled Asthma Inhaler Medication Technique-How to Take an Asthma Inhaler by America's Allergist

iv) a printable material (understandable and actionable), titled Asthma: How to Use A Metered Dose Inhaler, by FamilyDoctor.org

v) a printable material (understandable and poorly actionable), titled How to use an inhaler - no spacer, by MedlinePlus

vi) a printable material (poorly understandable), titled Inhaled Asthma Medications: Tips to Remember, by the American Academy of Allergy Asthma & Immunology

After seeing the randomly assigned audiovisual or printable material the participants will be administered a brief questionnaire to assess their understanding of how to use an inhaler and what actions to take based on the material.

4) Health Education Materials & Questionnaire - Colonoscopy - This includes a set of educational materials related to colonoscopy. Each consumer will be randomly assigned one of the six following materials:

i) an audiovisual material (understandable and actionable), titled Colonoscopy Patient Education Video by Krames

ii) an audiovisual material (understandable and poorly actionable), titled Colorectal Cancer Awareness by St. Vincent's Healthcare

iii) an audiovisual material (poorly understandable), titled Prepare for a Colonoscopy by The University of Texas MD Anderson Cancer Center

iv) a printable material (understandable and actionable), titled Getting Ready for Your Colonoscopy by West Chester Endoscopy Suite

v) a printable material (understandable and poorly actionable), titled Colonoscopy in the National Digestive Diseases Information Clearinghouse (NDDIC)

vi) a printable material (poorly understandable), titled Colonoscopy by the American College of Surgeons Division of Education

After viewing the randomly assigned audiovisual or printable material the participants will be administered a brief questionnaire to assess their understanding of a colonoscopy and what actions to take based on the material

The data collected from this project will be used to assess the construct validity of and inform revisions to the HIRS. The HIRS will be the first instrument that can assess the understandability and actionability of patient health education materials that can be incorporated into an EHR, including printable and audiovisual materials. Note that the materials to be assessed need not currently be incorporated into EHRs; for now, we are focusing on materials that have the potential to be incorporated into EHRs.

No claim is made that the results from this study will be generalizable in the statistical sense. Rather, the consumer testing will be informative and critical to ensuring we have developed a valid rating system by conducting consumer testing.

#### Estimated Annual Respondent Burden

Exhibit 1 presents estimates of the annualized burden hours for the participants' time to participate in this research. The Demographic and S-TOFHLA questionnaires will be completed by all 48 participants and takes 5 and 7 minutes, respectively, to complete. Each of the 48 participants will review 2 different health education materials and then answer the associated questionnaires for each material topic. Participants will review English-language materials related to inhaler use and colonoscopy. To review each material and answer the associated questionnaire requires 30 minutes (15 minutes to review the materials and 15 minutes to complete the questionnaire). The total annualized burden is estimated to be 58 hours.

Exhibit 2 presents the estimated annualized cost burden associated with the respondents' time to participate in this research. The total cost burden is estimated at \$1,237.

Exhibit 1. Estimated annualized burden hours

| Data Collection  | Number of respondents | Number of responses per respondent | Hours per response | Total burden hours |
|--|-----------------------|------------------------------------|--------------------|--------------------|
| Demographic Questionnaire                                | 48                    | 1                                  | 5/60               | 4                  |
| S-TOFHLA Questionnaire                                   | 48                    | 1                                  | 7/60               | 6                  |
| Health Education Materials & Questionnaire – Inhaler     | 48                    | 1                                  | 30/60              | 24                 |
| Health Education Materials & Questionnaire – Colonoscopy | 48                    | 1                                  | 30/60              | 24                 |
| Total  | 192                   | na                                 | na                 | 58                 |

Exhibit 2. Estimated annualized cost burden

| Data Collection  | Number of respondents | Total burden hours | Average hourly wage rate* | Total cost burden |
|--|-----------------------|--------------------|---------------------------|-------------------|
| Demographic Questionnaire                                | 48                    | 4                  | \$21.35                   | \$85              |
| S-TOFHLA Questionnaire                                   | 48                    | 6                  | \$21.35                   | \$128             |
| Health Education Materials & Questionnaire – Inhaler     | 48                    | 24                 | \$21.35                   | \$512             |
| Health Education Materials & Questionnaire – Colonoscopy | 48                    | 24                 | \$21.35                   | \$512             |

|       |     |    |    |         |
|-------|-----|----|----|---------|
| Total | 192 | 58 | na | \$1,237 |
|-------|-----|----|----|---------|

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\* Based upon the mean wage for all occupations, National Compensation Survey: Occupational wages in the United States May 2010, "U.S. Department of Labor, Bureau of Labor Statistics."

#### Estimated Annual Costs to the Federal Government

The total cost of this contract to the government is \$524,945, and the project extends over 3 years (July 19, 2010 to July 18, 2013). The data collection for which we are seeking OMB clearance will take place from February 1, 2013 to March 31, 2013. Exhibit 3 shows a breakdown of the total cost as well as the annualized cost for the data collection, processing and analysis activity for this entire contract.

#### Exhibit 3. Estimated Cost

| Cost Component               | Total Cost | Annual Cost |
|------------------------------|------------|-------------|
| Project Development          | \$66,447   | \$22,149    |
| Data Collection Activities   | \$129,547  | \$43,182    |
| Data Processing and Analysis | \$129,548  | \$43,183    |
| Publication of Results       | \$131,571  | \$43,857    |
| Project Management           | \$67,832   | \$22,611    |
| Total                        | \$524,945  | \$174,982   |

#### Request for Comments

In accordance with the Paperwork Reduction Act, comments on AHRQ's information collection are requested with regard to any of the following: (a) whether the proposed collection of information is necessary for the proper performance of AHRQ health care research and health care information dissemination functions, including whether the information will have practical utility; (b) the accuracy of AHRQ's estimate of burden (including hours and costs) of the proposed collection(s) of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information upon the respondents, including the use of automated collection techniques or other forms of information technology.

Comments submitted in response to this notice will be summarized and included in the Agency's subsequent request for OMB approval of the proposed information collection. All comments will become a matter of public record.

Dated: September 27, 2012

Carolyn M. Clancy, M.D.  
Director

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